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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,448

07/07/2003

Lawrence A. Shimp

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

07/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/614,448	Applicant(s) SHIMP, LAWRENCE A.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29,31-64 and 66-88 is/are pending in the application.
- 4a) Of the above claim(s) 2-29,31,36-51,53-63 and 66-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,32-35,52 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/18/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response and amendment filed 1 April 2008 to Office mailed 27 December 2007 is acknowledged and entered.

Withdrawal of Rejections based on Applicant's Amendments

2. In view of remarks and amendments filed 1 April 2008, the following objections and rejection in Office Action mailed 27 December 2007 are hereby withdrawn:

- Lack of written description requirement to Claims 1, 32-35, 52 and 64 under 35 U.S.C. §112, first paragraph;
- Lack of scope of enablement rejection to Claims 1, 32-35, 52 and 64 under 35 U.S.C. §112, first paragraph;
- Indefiniteness rejection to Claims 1, 32-35, 52 and 64 under 35 U.S.C. §112, 2nd paragraph; and
- Obviousness rejection to Claims 1, 32-35, 52 and 64 under 35 U.S.C. §103 (a) as obvious over the combined teachings from Sierra et al. (WO 98/31403) in view of Schankereli (U.S. Patent 5, 782,914 A) and further in view of Bertiger (US Patent 4,538,757).

Claims Status

3. Claims 30 and 65 remain cancelled.
4. Claim 1 has currently been amended.
5. Claims 1-29, 31-64 and 66-88 are pending.
6. Claims 2-29, 31, 36-51, 53-63 and 66-88 remain FINALLY withdrawn.
7. Claims 1, 32-35, 52 and 64 are examined on merits.

35 U.S.C. §102 Rejection

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. §102(b) as anticipated by Schankereli (U.S. Patent 5, 782,914 A).

Claim 1 recites a method to protect a property of a biological material during sterilization of said biological material via packaging said biological material under vacuum or in an “inert”, or a mixture of inert and reducing atmosphere and subsequently sterilizing said package under said atmosphere to reduce or inactivate “adventitious agents”.

Regarding Claim 1, Schankereli teaches a method for radiation sterilization of a vacuum-dried tissue contained in a pouch and further teaches that evacuation and/ or replacement of the atmosphere within the tissue package using argon or nitrogen limits free radical formation (i.e., oxidation) of the tissue during radiation sterilization, thus inhibiting chemical and physical damage to the tissue (Column 3, Lines 57 to Column 4, Line 22). Said material is lyophilized, vacuum dehydrated or freeze-dried prior to irradiation. Note that Schankereli explicitly teaches a method comprising radiation exposure of biological material to be processed under an inert or a mixture of an inert and a reducing atmosphere to prevent damage to the material being processed, wherein said damage is because of the potential oxidation of said material (i.e., tissue or a device) during the heat generating process (i.e., gamma sterilization). Thus, Schankereli teaches a method wherein, it is the oxidation of material being processed that is prevented which is the logic behind conducting said processes in presence of an inert or an inert mixed with a reducing atmosphere.

Therefore, the reference is deemed to anticipate the cited claim.

Claim Rejections - 35 USC §103

10. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 32-35, 52 and 64 are rejected under 35 U.S.C. § 103 (a) as obvious over the combined teachings from Schankereli (U.S. Patent 5, 782,914 A) in view of Bertiger (US Patent 4,538,757).

Claims recite a method to protect a property of a biological material during sterilization of said biological material via packaging said biological material under vacuum or in an “inert”, or a mixture of inert and reducing atmosphere and subsequently sterilizing said package under said atmosphere to reduce or inactivate “adventitious agents”. Claims further recite that the reducing atmosphere is comprised of one among hydrogen, hydrogen sulfide or carbon monoxide and inert atmosphere is comprised of nitrogen or argon, wherein the biological material is bone or tissue.

Schankereli’s teachings have already been discussed in items 08-09 *supra*. Schankereli, however, does not elaborate on presence of a specific inert or reducing gas (e.g., argon (Ar), helium (He) or nitrogen (N₂)) mixed with a reducing atmosphere. e.g., hydrogen (H₂), or in presence of a reducing atmosphere (e.g., hydrogen). Bertiger teaches that a reducing atmosphere prevents oxide formation (i.e., oxidation) and teaches a method to do so in the presence of an atmosphere that comprises 85% nitrogen and 15% hydrogen (Column 1, Lines 6-7; Lines 45-59 and Column 2, Lines 18-57). Note that both Schankereli and Bertiger teach processes comprising exposure of material to be processed to an inert or a mixture of an inert and a reducing atmosphere to prevent damage to the material being processed, wherein said damage is because of the potential oxidation of said material (i.e., tissue or a device) during the heat generating process (i.e., gamma sterilization, or soldering). Thus, in each case, it is the oxidation of material being processed that is prevented which is the logic behind conducting said processes in presence of an inert or an inert mixed with a reducing atmosphere, that is, they are solving the same problem in the same way. Note also, that the claims as currently presented require replacing the atmosphere of the biological material with either inert or mixture of an inert and reducing. Thus, combined teachings from Schankereli and Bertiger teach each and every element of the claimed invention because the purpose of surrounding the material is prevent the oxidation of the material.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify the teachings from Schankereli according to teachings from Bertiger; because as discussed in the previous paragraph, the cited prior art references teach a method to sterilize a biological material and additionally preventing the oxidation of said material(s) by conducting said processes in an inert or a mixture of an inert and a reducing atmosphere. Regardless of the material being treated, the logical reason to conduct the process is to prevent the damage to the material, which is also the objective of the instantly claimed method (i.e., to “protect one or more properties of the biological material).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings from Schankereli according to the teachings from Bertiger

to obtain a method to sterilize a biologically active material through gamma, or electron beam irradiation in an inert atmosphere or an atmosphere comprising a mixture of an inert and a reducing atmosphere (e.g., mixture of nitrogen and hydrogen), wherein said biological material was packaged in an unsealed or sealed package, dried through lyophilization, or freeze-drying; and subsequently said packaged biological material kept in an inert atmosphere comprising either vacuum or inert gases or in an atmosphere of inert gases mixed with hydrogen, prior to said radiation; because Bertiger supplements Schankereli's teachings since Bertiger teaches preventing oxidation of the material being processed because of the interaction of heat produced during each of the gamma irradiation, or soldering). The prior art references discussed *supra* do not teach exactly the same dimensions for each of the parameters for irradiation-mediated sterilization of a biologically active material. However, the adjustment of particular conventional working conditions (e.g., irradiation dosage, temperature during irradiation, means to dry the sample and type of inert gas atmosphere; torr of negative pressure for vacuum or exact same volume to volume mixture of inert and reducing gas, but do teach a vacuum and a certain percentage of nitrogen and hydrogen in the mixture of inert and reducing gaseous mixture) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan. In view of the fact that the applicant's invention also recites a method to sterilize a biologically active material and the basic principle of said method is to protect one or more properties of said material during the claimed process via prevention of oxidation of said material by conducting said process in an atmosphere comprising mixture of an inert and a reducing gas.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

12. For reasons aforementioned, no Claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657
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18 July 2008

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657